UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

SUSAN T. SCHOUEST,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION G-13-203
	§	
MEDTRONIC, INC., *et al.,*	§	
	§	
Defendants.	§	

MEMORANDUM AND ORDER

Pending before the court is defendants' motion to dismiss plaintiff's first amended complaint. Dkt. 50. After considering the motion, all responses, and the applicable law, the court is of the opinion that the motion should be GRANTED.

I. BACKGROUND

This case was originally assigned to Judge Gregg Costa in the Galveston District of the Southern District of Texas, but was reassigned to this court in October 2014. Dkt. 64. When the court considered defendants' first motion to dismiss plaintiff's original complaint, it wrote a substantial opinion including an analysis of how the preemption doctrine applied to the claims in the case. Dkt. 48. At that time, the court allowed the plaintiff to replead her claims. Because the claims are the same in the amended complaint, and in the interest of judicial economy and consistency, this court will rely upon the prior court's statement of facts, law, analysis, and some of its conclusions in the disposition of the present motion, as appropriate.

In summary, this case arises out of a surgery plaintiff Susan Schouest ("Schouest") underwent in December 2006, in which her physician performed an "off-label" surgery with defendants Medtronic Inc.'s and Medtronic Sofamor Danek USA, Inc.'s (collectively "Medtronic") Infuse Bone

Graft ("Infuse") device.[1] Dkt. 49 at 7–8, 104. In June 2009, Schouest was diagnosed with injuries arising out of the 2006 surgery, for which she had to undergo two additional surgeries in August 2009 and other treatment. *Id.* at 104. As a result of the injuries and treatment, Schouest brought nine claims against Medtronic relating to its promotion of Infuse for off-label uses. Medtronic filed a motion to dismiss plaintiff's claims on the basis of preemption, a failure to meet federal pleading standards, and statute of limitations. Dkt. 14. The court concluded that several of Schouest's claims avoided preemption all together, others claims had to be dismissed outright as preempted, and some claims might avoid preemption with proper allegations. The court did not consider whether Schouest's claims met the federal pleading standards at the time because it allowed Schouest a chance to amend her complaint. Schouest then filed an amended complaint (Dkt. 49), which is the subject of defendants' present motion to dismiss (Dkt. 50). Schouest has responded to the motion to dismiss and it is ripe for disposition.

II. LEGAL STANDARD

As stated in the court's prior memorandum and order, Federal Rule of Civil Procedure 12(b)(6) allows dismissal if a plaintiff fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). In evaluating a Rule 12(b)(6) motion, the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999)). The court does not look beyond the face of the pleadings to determine whether the plaintiff has stated a claim. *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). To survive a motion to dismiss, a claim for relief must be "plausible on its face." *Bell Atl. Corp. v.*

[1] An off-label procedure is one that uses a medical device in a procedure in a way not expressly approved by the FDA. Dkt. 1 at 3.

Twombly, 550 U.S. 544, 570 (2007). If the face of the complaint makes it apparent that federal law preempts a plaintiff's claims, dismissal is warranted at the Rule 12 stage. *See Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012) (explaining that if "the complaint itself establishes the applicability of a federal-preemption defense," the issue "may properly be the subject of a Rule 12(b)(6) motion); *Frank v. Delta Airlines, Inc.*, 314 F.3d 195, 203 (5th Cir. 2002) (reversing trial court and rendering judgment on motion to dismiss because federal law preempted plaintiff's state law claims).

III. ANALYSIS

Medtronic asserts that, to the extent that Schouest's claims are not preempted, they do not satisfy federal pleading standards or are time-barred. Schouest asserts that her claims are not time barred and that they meet federal pleading standards.

A. Preemption

The court's prior memorandum and order clearly laid out the narrow circumstances under which some of Schouest's claims could avoid preemption. For Schouest to avoid preemption of her general negligence claim, she must point to a state law duty to report adverse events *and* what FDA reporting regulations Medtronic allegedly violated. Dkt. 48 at 23–25. Schouest's amended complaint does not point to a duty to report adverse events or allege any FDA reporting regulations that Medtronic violated. Dkt 49 at 110. Therefore, any general negligence claim that Schouest has attempted to plead is preempted. Medtronic's motion to dismiss Schouest's general negligence claim is GRANTED.

The court also found that Schouest could avoid preemption of the express breach of warranty claim, but only to the extent that Schouest seeks to recover based on false warranties that Medtronic

voluntarily and falsely made beyond the federally approved warning, and *if* Schouest provides a description of what specific warranties Medtronic made to Schouest or her physicians. Dkt. 48 at 28. In the original complaint, Schouest alleges that Medtronic "expressly . . . warranted to physicians and other members of the general public and medical community that such off-label uses, including the type of off-label procedure that Plaintiff underwent, [were] safe and effective." Dkt. 1 at 23. However, the court found that this language failed to allege what specific warranty was made. In the amended complaint Schouest asserts the same language, but adds another sentence in a later paragraph: "Medtronic made express warranties regarding the safety and efficacy of the Infuse Bone Graft in off-label uses." Dkt. 49 at 111. This new statement is more broad that than description of the warranty that the court previously rejected because it does not even refer to the particular procedure Schouest underwent. Schouest's amended complaint fails to allege what express warranties, if any, were made directly to Schouest or her physicians. Accordingly, Medtronic's motion to dismiss the express warranty claim is GRANTED.

Finally, the court found that Schouest's claim for violating Texas Consumer Protection Laws could avoid preemption if the alleged deceptive act was in the promotion of the Infuse device and Schouest specified which statutory duties Medtronic allegedly violated, which she had not done in the original complaint. *Id.* at 28. In the amended complaint, Schouest fails to specify which statutory duty Medtronic allegedly violated. The citations included in the amended complaint, including the original citations that were insufficient, either cite entire Acts or cite Regulatory provisions not relevant to specifying a statutory duty as directed by the court. *Compare* Dkt. 1 at 29–30, *with* Dkt. 49 at 129–30. Accordingly, Medtronic's motion to dismiss Schouest's Texas Consumer Protection Laws claim is GRANTED.

III. CLAIMS SUBJECT TO RULE 9B PLEADING STANDARDS

A. Legal Standard

The court will apply Federal Rule of Civil Procedure Rule 9(b) to Schouest's fraud, constructive fraud and negligent misrepresentation claims. The court noted previously that there was a split in the Fifth Circuit as to whether the Rule 9(b) particularity standards applied to constructive fraud and negligent misrepresentation claims. One reason the court declined to consider whether the claims met the federal pleading standards in its previous order was to provide Medtronic a chance to argue why Rule 9(b) should apply to the constructive fraud and negligent misrepresentation claims. Dkt. 48 at 31 n.9. Medtronic has argued that Rule 9(b) applies to those claims and Schouest does object or argue otherwise. Therefore, Schouest has waived this argument. *Am. Realty Trust, Inc. v. Travelers Cas. and Sur. Co. of Am.*, 362 F. Supp. 2d 744, 749–52 (N.D. Tex. 2005) ("Rule 9(b) operates to require dismissal of a negligent misrepresentation claim only when (1) a plaintiff waives arguments to the contrary or (2) the inadequate fraud claim is so intertwined with the negligent misrepresentation claim that it is not possible to describe a simple redaction that removes the fraud claim while leaving behind a viable negligent misrepresentation claim.").

As the court previously stated, Rule 9(b)'s heightened pleading standard requires that certain claims be alleged "with particularity." That rule usually requires that the plaintiff identify "the who, what, when, where, and how of the alleged fraud." *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 266 (5th Cir. 2010) (internal quotation marks and citations omitted). Such information should be readily available prior to discovery to the typical fraud plaintiff who was the direct recipient of fraudulent information. *See* 5A Charles Alan Wright et. al., Federal Practice and Procedure § 1297 (3d ed. 2004) (explaining that requiring that fraud be pled with precision allows

defendants to understand "the acts or statements or failures to disclose" on which the plaintiff actually relied). While the court outlined an exception to the strict Rule 9(b) standard that the plaintiff might try to utilize to relax the standard, Schouest has not argued for the application of any such exception and the court will apply Rule 9(b) in its traditional form.[2]

Additionally, because the alleged fraudulent misrepresentations were not made directly to the plaintiff, but rather to her physician who relied on them, the fraud allegations are based on an "intermediary theory." *See Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 433 ("[W]hen the drug company positively and specifically represents its product to be free and safe from all dangers of addiction, and when the treating physician relies upon that representation, the drug company is liable when the representation proves to be false and harm results.").

B. Fraud

The elements of a fraud claim are that the defendant 1) made a material representation that was false; 2) knew the representation was false or made it recklessly as a positive assertion without any knowledge of its truth; 3) intended to induce plaintiff to act upon the representation; and 4) the

[2] The court explained that a number of courts have recognized that the heightened pleading standards of Rule 9(b) should be relaxed "upon a showing by the plaintiff that he or she is unable, without pretrial discovery, 'to obtain essential information' peculiarly in the possession of the defendant." *Freitas v. Wells Fargo Home Mortg., Inc.,* 703 F.3d 436 (8th Cir. 2013) (citation omitted) (though declining to relax the particularity requirement in the context of that case). In qui tam cases, for example, the Fifth Circuit has explained that Rule 9(b) is not a "straitjacket" because relators often do not possess the billing information submitted to the federal government at the pleading stage—"a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *but see U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 768 (S.D. Tex. 2010) (citing *U.S. ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 n.6 (5th Cir. 2008)) ("In the Fifth Circuit, the pleading standard is not relaxed when such information is available from third party entities and individuals."). The Seventh Circuit has relaxed the pleading requirement for certain RICO cases under the same lack of pre-discovery-access rationale. *See Corley v. Rosewood Care Ctr., Inc. of Peoria*, 142 F.3d 1041, 1050–51 (7th Cir. 1998) (relaxing particularity requirements of Rule 9(b) when RICO plaintiff lacked access to all facts necessary to detail claim).

plaintiff actually and justifiably relied upon the representation and thereby suffered injury. *Ernst & Young, L.L.P. v. Pac. Mut. Life Ins. Co.*, 51 S.W.3d 573, 577 (Tex. 2001).

Medtronic argues that Schouest has not met the particularity standards because she has not asserted a specific misrepresentation, and any such misrepresentation has not been alleged to have been made directly to the physician. Dkt. 50 at 26. Even if a misrepresentation to the physician could be identified, Medtronic argues, reliance on it was not justifiable because the warning on the device that is cited in Schouest's complaint warns that the Infuse cannot be used without a certain component that the physician did not use. *Id.* at 16.

Schouest asserts that Medtronic edited and drafted nearly all of the original medical literature that was published on the Infuse device, that the literature was widely distributed and cited in studies, and that the literature "misrepresented the safety of Infuse for both on- and off-label uses" and concealed "truthful data about adverse events." Dkt. 53 at 11. Schouest also alleges that Medtronic representatives provided physicians with their literature, encouraged use of off-label procedures, and trained physicians on using the Infuse device in off-label procedures. *Id.* at 12. Schouest further asserts that Medtronic paid physicians to promote off-label uses and fund studies that misrepresented the safety and effectiveness of Infuse for various uses, including the procedure that Schouest underwent. *Id.* at 12–13. Schouest claims that all of her allegations show "the particular mechanisms by which Medtronic spread its affirmative misrepresentations throughout the medical community and to Plaintiff and Plaintiff's physician." *Id.* at 13. Schouest's physician provided an affidavit that included statements that "Medtronic promoted and represented that the Infuse Bone Graft was safe for the type of fusion performed on Ms. Schouest" and that the physician "made the decision to use the Infuse Bone Graft based upon [the physician's] experience and training and the

representations made by Medtronic and its representatives." Dkt. 49-1. All of these allegations, Schouest claims, provide the who, what, when, where and how that support her claims of fraud and constructive fraud. *Id.*

Fifth Circuit "precedent interprets Rule 9(b) strictly, requiring the plaintiff to specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 207 (5th Cir. 2009). The court need not analyze whether the alleged fraudulent misrepresentation has been plead with sufficient specificity because plaintiff has not identified the speaker or stated when and where the statements were made. For example, Schouest's complaint does not identify the Medtronic employee who came into physician's office to make the representations on a specific day, or even point to a particular piece of the literature that contains a fraudulent representation. Were this claim being analyzed under a lesser standard that did not require specifying, the who, what, when, where and how, the court might reach a different conclusion. *See, e.g.,* n.1. However, Schouest has not sought review under Rule 8(a) or even argued for application of an exception to Rule 9(b). Under a strict Rule 9(b) analysis, Schouest has not sufficiently pled her fraud claim.

Further, the court is not persuaded that Schouest has plead a fraud claim based on the lack of adverse events included in its literature. Schouest has failed to plead what literature she complains of other than studies not authored by Medtronic, she fails to plead any legal requirement that adverse events be included in literature generally, and Schouest's reference to a Senator's opinion disparaging the practice of not publicizing adverse events does not alone make it a fraudulent representation. *Id.* at 12.

Plaintiff's fraud claim does not meet the Rule 9(b) standard. Accordingly, Medtronic's motion to dismiss the fraud claim is GRANTED.

C. Constructive Fraud

Under Texas law, "constructive fraud is the breach of some legal or equitable duty which, irrespective of moral guilt, the law declares fraudulent because of its tendency to deceive others, to violate confidence, or to injure public interests." *Archer v. Griffith*, 390 S.W.2d 735, 740 (Tex. 1964). Schouest does not dispute that Rule 9(b) applies to this claim.

Schouest argues that Medtronic had a unique knowledge concerning the safety and effectiveness of Infuse and, despite this knowledge, it continued to "intentionally misrepresent material facts concerning the safety and effectiveness of Infuse Bone Grant and the adverse events associated with its use." Dkt. 49 at 125. In support, Schouest points to articles that were published in 2011 and 2012 that suggest that industry-sponsored publications did not report adverse events of Infuse, or reported fewer adverse events than non-industry publications reviewing Infuse. Dkt. 49 at 125–27. Medtronic's "misrepresentations induced Schouest and the medical community, including [Schouest's physician] to rely on these misrepresentations." Dkt. 49 at 127. Schouest claims that "Medtronic took advantage of their dominant position of knowledge with regard to Schouest and engaged in constructive fraud in their relationship with" Schouest and her physician, in that her physician "reasonably relied on the superior knowledge of Medtronic regarding the safety and effectiveness of the Infuse product for utilization in" the procedure plaintiff underwent. Dkt. 49 at 127. Plaintiff argues that Medtronic's acts constitute misbranding under 21 U.S.C. §§ 331(a) and 333(a)(2) and "constitute a breach of duty subjecting Medtronic to civil liability . . . under the theory of constructive fraud." Dkt. 49 at 127.

Medtronic responds that Schouest has not pled the existence of either a fiduciary duty or a confidential interest to Schouest or her physician sufficient to support a constructive fraud claim. Dkt. 50 at 22. Additionally, Medtronic asserts that plaintiff has failed to allege a specific misrepresentation with a causal connection to the injury. *Id.*

Schouest does not allege how Medtronic's representations violate the only law cited, 21 U.S.C. §§ 331(a), relating to misbranding of products. In terms of the alleged representations, the amended complaint claims that Medtronic intentionally misrepresented material facts concerning the safety and efficacy of Infuse and adverse events associated with its use. Yet, Schouest never specifies what those material facts were are or how they misrepresented the truth. For example, Schouest points to no statement from Medtronic representing anything about the bone growth she experienced. Schouest has not alleged facts to show that the failure to report adverse events creates some kind of legal or equitable liability. Though Schouest points to articles that cover out a suspiciously low or absent number of adverse results in studies of Infuse, Schouest does not allege that these studies were conducted by Medtronic (albeit, they were allegedly sponsored by the "industry"), and such articles do not allege a breach of a legal or equitable duty owed by Medtronic. Schouest must assert more to plead this claim with particularity under a strictly construed Rule 9(b), in particular, facts asserting the breach of a legal or equitable duty. Accordingly, Medtronic's motion to dismiss Schouest's constructive fraud claim is GRANTED.

D. Negligent Misrepresentation

In Texas, the four elements to establish a negligent misrepresentation claim include:

> (1) [a] representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; (2) the defendant supplies "false information" for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the

> information; and (4) the plaintiff suffers pecuniary loss by justifiably relying on the representation.

Gen. Elec. Capital Corp. v. Posey, 415 F.3d 391, 395–96 (5th Cir. 2005) (internal quotations omitted). Schouest does not dispute Medtronic's assertion that Rule 9(b) applies.

Schouest argues that she has alleged multiple false representations that Medtronic made to Schouest and Schouest's physician that serve as the basis of this claim. Dkt. 53 at 7. Schouest argues that Medtronic engaged in activity to conceal adverse events in order to promote the off-label uses of Infuse, such as the procedure Schouest underwent, as safe and effective, though Medtronic knew it was not safe and effective. Dkt. 53 at 7. Schouest also argues that Medtronic promoted off-label uses of Infuse through Opinion Leaders at trainings and conferences, through marketing teams, and through articles. *Id.* at 7–8. Schouest claims her physician relied on literature and representations made by Medtronic employees and sales representatives. *Id.* Medtronic responds that Schouest has failed to plead any specific misrepresentation as required by Rule 9(b).

Despite claiming that there were multiple false representations made to Schouest and her physician, Schouest never identifies what the specific misrepresentations were. Schouest does assert that Medtronic represented that the off-label use of Infuse was safe, when it was not safe, but this is conclusory and general. Schouest also fails to allege with particularity who made the representation, and when or where the misrepresentations were made. While this claim may have survived under a lesser pleading standard, Schouest has not alleged facts to meet the elements of the claim with the particularity required by Rule 9(b). Therefore, Medtronic's motion to dismiss Schouest's claim for negligent misrepresentation is GRANTED.

V. REMAINING CLAIMS

The remaining claims in this case are for gross negligence and unjust enrichment. Because the court has dismissed all negligence claims upon which gross negligence could be predicated, it must also dismiss Schouest's gross negligence claim. This is because "one's conduct cannot be grossly negligent without being negligent." *Trevino v. Lightning Laydown, Inc.*, 782 S.W.2d 946, 949 (Tex. App.—Austin 1990, writ denied). Accordingly, Medtronic's motion to dismiss Schouest's gross negligence claim is GRANTED.

Additionally, because unjust enrichment is not a stand-alone claim, and there are no remaining claims upon which it can be based, the claim must be dismissed. *See Walter v. Cotter Props., Inc.*, 181 S.W.3d 895, 900 (Tex. App.—Dallas 2006). Medtronic's motion to dismiss Schouest's unjust enrichment claim is GRANTED.

Finally, because the court has disposed of all claims as either preempted or for not meeting Rule 9(b), it need not determine whether any claims are barred by the statute of limitations.

VI. CONCLUSION

For the foregoing reasons, Medtronic's motion to dismiss (Dkt. 50) all claims under Rule 12(b)(6) is GRANTED.

It is so **ORDERED**.

Signed at Houston, Texas on March 20, 2015.

Gray H. Miller
United States District Judge